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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2017-0005]

Preventing Undeclared Allergens: A Strategic Approach to
Reducing Recalls

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notification of Public Meeting.

SUMMARY: The Food Safety and Inspection Service (FSIS), with participation from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), international partners, and academic institutions, is hosting a public meeting to discuss the prevention of undeclared allergens in FSIS-regulated product. Specifically, the meeting will address the continued occurrence of product recalls due to undeclared allergens and best practices for preventing the presence of undeclared allergens in FSIS-regulated products. Topics will focus on FSIS policy and enforcement regarding undeclared allergens, labeling compliance, best practices for prevention, and emerging issues. Industry and interested individuals, organizations, and other stakeholders are invited to participate in the meeting and comment on these topics.

Dates: The public meeting will be held on Thursday, March 16, 2017, 8:00 a.m. to 5:30 p.m. EST.

Addresses: The meeting will be held at the Jefferson Auditorium in the South Building, U.S. Department of Agriculture (USDA), 14th & Independence Avenue SW., Washington, DC 20250. The South Building is a Federal facility, and attendees should plan adequate time to pass through the security screening systems. Attendance is free. Non-USDA employees must enter through the Wing 3 entrance on Independence Avenue. Attendees must be pre-registered for the meeting (and check-in onsite the day of the meeting) and show a valid photo ID to enter the building. See the pre-registration instructions under "Registration and Meeting Materials." Only registered attendees will be permitted to enter the building.

For Further Information Contact: Evelyn Arce, Outreach and Partnership Analyst, Office of Outreach, Employee Education and Training, FSIS, 1400 Independence Ave., SW Mail Stop 3778, Washington, DC 20250; Telephone: (202) 418-8903; Fax: (202) 690-6519; Email: Evelyn.Arce@fsis.usda.gov.

SUPPLEMENTARY INFORMATION

I. Background

More than 170 foods have been reported to cause allergic reactions. However, eight of the most common allergenic foods, usually referred to as the "Big 8," account for 90 percent of all food allergic reactions and are the sources from which many other allergenic ingredients are derived. The Big 8 food

allergens are wheat, crustacean shellfish (e.g., shrimp, crab, lobster), eggs, fish, peanuts, milk, tree nuts (e.g., almonds, pecans, walnuts), and soybeans.

Food allergies are increasing in reported prevalence and present a significant public health problem that affects both adults and children. Food allergens may be ingredients in meat, poultry, and egg products and thus the presence of undeclared allergens in these products may result in adverse health outcomes for certain individuals. FSIS-regulated establishments are required to declare all ingredients, including allergens, on the product label (9 CFR 317.2(f)(1), 381.118(a)(1), and 590.411(c)(1)). If FSIS finds that product under its jurisdiction in commerce contains undeclared allergens, FSIS will request that the establishment recall the product.

Since 2008, FSIS has seen a notable increase in the number of recalls due to undeclared allergens in FSIS-regulated products. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, meat, poultry, and egg products that contain an allergen not declared on the product label are adulterated because, to individuals who are allergic to the allergen, the products bear or contain a poisonous or deleterious substance (21 U.S.C. 453(g)(1), 601(m)(1), and 1033(a)(1)). Furthermore, the meat, poultry, and egg products also are misbranded because the

labeling is false and misleading (21 U.S.C. 453(h) (1), 601(n) (1) and 1033(1)). The presence of undeclared allergens in product is often preventable, as it results from incorrect labeling or packaging of products, due to unexpected product and ingredient changes, cross-contamination of product during processing, and other types of procedural and human error.

To address the presence of undeclared allergens in product and the increasing number of recalls involving undeclared allergens, FSIS, with speakers from FDA, CDC, international partners and academic institutions, is hosting a public meeting to highlight the problem of undeclared allergens in food, food allergy trends, and best practices for preventing undeclared allergen-related recalls.

In addition to holding this public meeting, FSIS has developed a compliance guideline to assist establishments in addressing the hazards posed by allergens in their products, available at:

<https://www.fsis.usda.gov/wps/wcm/connect/f9cbb0e9-6b4d-4132-ae27-53e0b52e840e/Allergens-Ingredients.pdf?MOD=AJPERES>. FSIS updates this guidance as necessary as new information becomes available.

II. Registration and Meeting Materials

There is no fee to register for the public meeting, but pre-registration is mandatory for participants attending in-

person. On-site registration will not be permitted. Early registration is recommended as space is limited. All attendees must register online by emailing AllergenPublicMeeting@fsis.usda.gov by March 9, 2017.

FSIS will finalize an agenda on or before the meeting dates and post it on the FSIS Web page at <http://www.fsis.usda.gov/meetings>.

III. Public Comments and Participation in Meetings

Public Comments: Oral Comments

Stakeholders will have an opportunity to provide oral comments during the public meeting. Due to the anticipated high level of interest in the opportunity to make public comments and the limited time available to do so, FSIS will do its best to accommodate all persons who wish to express an opinion. FSIS encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative.

Public Comments: Written Comments

Any stakeholders wishing to submit written comments before or after the meeting can do so on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], using any of the following methods: Electronically - go to <http://www.regulations.gov> and follow the online instructions for submitting comments; Mail, including CD-ROMS - send to

Docket Clerk, USDA, FSIS Docket Room, 1400 Independence Avenue, SW, Patriots Plaza III, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700; Hand- or courier-delivered items - deliver to the Docket Clerk, USDA, FSIS Docket Room at Patriots Plaza III, 355 E Street, SW., Room 8-164, Washington, DC 20250, between 8:30 a.m. and 4:30 p.m., Monday through Friday.

All items submitted by mail or electronic mail must include the Agency name and docket number: FSIS- 2017-0005. Written comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to

<http://www.regulations.gov>. For access to background documents or written comments received, go to the FSIS Docket Room at Patriots Plaza III, 355 E Street, SW, Room 8-164, Washington, DC 20250, between 8:30 a.m. and 4:30 p.m., Monday through Friday.

Question-and-Answer Periods: Time has been allotted for audience questions after most presentations delivered during the meeting. Participants will have the opportunity to ask questions via a microphone in the auditorium.

IV. Transcripts

The transcript of the proceedings from the public meeting will become part of the administrative record. As soon as the meeting transcripts are available they will be accessible on the FSIS website at

<http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings>. The transcripts may also be viewed at the FSIS Docket Room at the address listed above.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

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Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail:

U.S. Department of Agriculture
Director, Office of Adjudication
1400 Independence Avenue, SW

Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done at Washington, DC on: February 9, 2017.

Alfred V. Almanza,
Administrator

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